



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0091]

Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance entitled "Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods." The document provides guidance to firms that manufacture, process, pack, or hold human foods or direct-human-contact animal foods intended for distribution to consumers, institutions, or food processors. This guidance does not apply to egg producers and other persons who are covered by FDA's final rule "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation." The guidance addresses testing procedures for Salmonella species (spp.) in human foods (except shell eggs) and direct-human-contact animal foods, and the interpretation of test results, when the presence of Salmonella spp. in the food may render the food injurious to human health.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition, (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed

adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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240-402-2022.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of March 23, 2011 (76 FR 16425), FDA made available a draft guidance entitled "Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods" and gave interested parties an opportunity to submit comments by June 21, 2011. The Agency reviewed and evaluated these comments and has modified the guidance where appropriate.

This guidance is intended for firms that manufacture, process, pack, or hold human foods or direct-human-contact animal foods intended for distribution to consumers, institutions, or food processors. The guidance does not apply to egg producers and other persons who are covered by FDA's final rule "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage,

and Transportation" (21 CFR part 118; the shell egg final rule). The guidance addresses testing procedures for Salmonella spp. in human foods (except shell eggs) and direct-human-contact animal foods, and the interpretation of test results, when the presence of Salmonella spp. in the food may render the food injurious to human health. FDA issued separate guidances in December 2011 and July 2011, respectively, entitled "Guidance for Industry: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage and Transportation," which provides guidance to egg producers on how to comply with certain provisions contained in the shell egg final rule, including provisions for environmental and egg testing for Salmonella Enteritidis; and "Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation," which responds to questions FDA has received on the shell egg final rule since its publication and includes guidance on environmental and egg testing for Salmonella Enteritidis.

II. Significance of Guidance

The final guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on testing for Salmonella spp. in human foods and direct-human-contact animal foods. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding the guidance. It is only

necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Always access an FDA document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: March 5, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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